

## REMARKS

Claims 14 and 32-34 are currently amended. Claims 15, 35 and 36 are cancelled. It is respectfully submitted that the arguments herein place this case in condition for allowance. The Amendments should be entered as they place the case in better condition for appeal. Reconsideration of the application is urged.

### I. The Rejection of Claim 36 under 35 U.S.C. 112

Claim 36 is cancelled. Accordingly, the rejection is moot.

### II. The Rejections of Claim 36 under 35 U.S.C. 102(b)

Claim 36 is cancelled. Accordingly, all rejections under 35 U.S.C. 102(b) are moot.

### III. The Rejection of Claims 14-30, 32-36 under 35 U.S.C. 103(a)

Claims 14-30, 32-36 stand rejected under 35 U.S.C. 103(a) as being obvious over Kaasgaard et al (US 2004/0175812A1). The Office asserts that Kaasgaard (US 2004/0175812A1) qualifies as prior art only under 35 U.S.C. 102(e) and that the rejection under 35 U.S.C. 103(a) may be overcome by . . . showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a).

Applicants submit the following showing under 103(c), which is in accordance with the "Guidelines Setting Forth A Modified Policy Concerning The Evidence Of Common Ownership, Or An Obligation Of Assignment To The Same Person, As Required By 35 U.S.C. 103(c)", set forth in the Official Gazette (December 26, 2000). Applicants hereby confirm that the instant application and Kaasgaard (both US 2004/0175812 and WO 2003/014339) were, at the time the invention of the instant application was made, owned by or subject to an obligation of assignment to Novozymes A/S.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

Applicants draw the Examiner's attention to WO 2003/014339 which is related to Kaasgaard (2004/0175812).

### IV. The Rejection of Claims 35 and 36 under 35 U.S.C. 103(a)

Claims 35 and 36 stand rejected under 35 U.S.C. 103(a) as being obvious over CH 667673.

Claims 35 and 36 are cancelled. Accordingly the rejection is moot.

**V. The Rejection of Claims 14, 15, 17-20, 24, 29, 30, 34 and 36 under 35 U.S.C. 103(a)**

Claims 14, 15, 17-20, 24, 29, 30, 34 and 36 stand rejected under 35 U.S.C. 103(a) as being obvious over Clarke (US 5,260,202). Applicants traverse this rejection.

"Section 103 forbids issuance of a patent when 'the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.'" *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 298, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3) the level of skill in the art, and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

The Supreme Court stated that "[o]ften, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR*, 550 U.S. at 418. The Court also noted that "[t]o facilitate review, this analysis should be made explicit." *Id.* at 418. (Citing *In re Kahn*, 441 F.3d 977, 988 (Fed Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")). However, "the analysis need not seek out precise teachings directed to a specific subject matter of the challenged claim, for a court can take into account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.*

In rejecting claims under 35 U.S.C. § 103(a), the examiner bears the initial burden of establishing a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir 1992); see also *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984). Only if this initial burden is met does the burden of coming forward with evidence or argument shift to the appellant. See *Oetiker*, 977 F.2d at 1445; see also *Piasecki*, 745

F.2d at 1472. Obviousness is then determined on the basis of the evidence as a whole and the relative persuasiveness of the arguments. *Id.*

Initially, the independent claims have been amended to refer to *Bacillus*.

Clarke relates to the recoverable yield of recombinant human albumin in the fermentation of genetically engineered yeast that expresses the albumin and secretes it into the culture medium is increased by the addition of a stabilizing agent. Clarke is deficient in that it does not refer to *Bacillus*.

The conclusion drawn by the Examiner that "clearly one of skill is aware of scaling up fermentation broths" amounts to nothing more than general statements that the claimed *Bacillus* fermentation method would be expected, without providing any evidence of such an effect. The general statement made by the Examiner lacks the specificity required to support a legal conclusion of obviousness and are thus insufficient to establish *prima facie* obviousness. See KSR (holding that a "patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the art . . . it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed invention does." Here, Clarke does not even refer to *Bacillus* in accordance with the present claims.

Further, it is speculative that what may work in a yeast fermentation would necessarily work for bacillus, an entirely different organism.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. § 103(a). Applicants respectfully request reconsideration and withdrawal of the rejection.

#### **VI. The Rejection of Claims 35 and 36 under 35 U.S.C. 103(a)**

Claims 35 and 36 stand rejected under 35 U.S.C. 103(a) as being obvious over the combination of DD 0153495 in view of Schreiber (U.S. 4,016,039), Brothers (US 4,673,647), GB 1001173 in further view of Boyer (US 5,385,837).

Claims 35 and 36 are cancelled. Accordingly the rejection is moot.

#### **VII. Conclusion**

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning

this amendment or application. Should any additional fees be due, the USPTO is authorized to charge the deposit account of Novozymes North America, Inc --No. 50-1701.

Respectfully submitted,

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